ENGINEERING ANALYSIS

Source Name: **AMPAC Fine Chemicals Virginia, LLC** Permit No.: **50856-19**

Source Location: **Petersburg, Virginia** Engineer: **CLM**

Date: **September 28, 2016**

I. Introduction and Background

A. Company Background

AMPAC Fine Chemicals Virginia, LLC is the new owner of the bulk pharmaceutical manufacturing facility previously owned by B.I. Chemical (and subsequently bought and sold by UniTao Pharmaceuticals, LLC) at 2820 N. Normandy Drive, Petersburg, VA. The facility was originally permitted on November 1, 1977, and stopped production under B.I. Chemical ownership in 2014. UniTao Pharmaceuticals, LLC submitted a change in ownership form in November, 2014, as well as the permit application on July 1, 2016. AMPAC Fine Chemicals Virginia, LLC submitted a change of ownership form on September 21, 2016.

The company is located on a site which is suitable from an air pollution standpoint. It is located in Petersburg, which is an attainment area for all pollutants. The last air inspection was conducted at the facility on April 3, 2014, and the facility was found to be in compliance. No Local Governing Body Certification Form was required since this is not a Greenfield source.

The correct permit fee of $841 for a SOP amendment was received on July 1, 2016 and credited on July 6, 2016.

B. Proposed Project Summary

DEQ received a state operating permit amendment application, dated July 1, 2016, requesting that a permit condition be added to allow the facility to recommence operations without being required to use the existing RTO Control System (consisting of an RTO followed by an acid gas scrubber) for processes in Buildings S1 (Specialty Building), S2 (Hydrogenation Building), and S3 (Production Building). Since the construction of Building S5 in 2006 was permitted relying on the RTO Control System as BACT, any processes in that building would still be required to vent to the RTO at all times. (Note: The installation of the RTO Control System to control all bays at the plant replaced a “voluntary MACT device”-- carbon beds followed by scrubber-- used to avoid major source status under MACT Subpart GGG).

Condition 6 of the draft permit allows the facility to bypass the RTO Control System, provided that VOC emissions are less than 25 tons per year, based on a 12-month rolling average. Hazardous air pollutants would continue to be limited to 9.4 tons/yr individual HAP, and 24.4 tons/yr total HAP. The 25 ton per year VOC limit was determined based on the new source exemption level of 25 tons/yr for VOC. The new source VOC exemption level was chosen rather than the project VOC exemption level because though it was never administratively shut down, this is not an active plant and has not produced any pharmaceutical products in more than 2 years. Although this does not constitute an exemption determination, production at the facility ceased under B.I. Chemical ownership in 2014, and when it does resume, it will be on a very small scale (on the order of a single 100 liter batch reactor). The emissions from the initial manufacturing process will not warrant the operation of the RTO Control System until production is ramped up to levels more in line with the previous production capacity at B.I. Chemical. Instead, emissions from the processes in Buildings S1, S2, and S3 will be

controlled by the condensers and scrubbers that were originally installed with the process equipment and were deemed to be BACT at that time they were permitted. This alternate operating scenario is considered to be temporary as production resumes. If AMPAC Fine Chemicals Virginia, LLC would like to further increase emissions while continuing to bypass the RTO Control System for Buildings S1, S2, and S3, this will be considered a change in the method of operation, and a new BACT analysis will be required.

C. Process and Equipment Description

The facility is designed to manufacture pharmaceuticals using variously configured batch processes located in "bays". The process equipment located in each bay is described in the equipment list. VOC emissions are controlled using combinations of condensers and scrubbers, with all bays capable of venting to the facility's RTO Control System. Particulate emissions are controlled using baghouses. A leak detection program is required by the permit. Wastewater treatment is addressed. The following table highlights permit changes:

Condition Number (9/27/13 SOP)	Condition Number (Draft Permit)	Description of Change
1	Equipment List	The following equipment has been deleted since it has been removed from the plant: Milling Building: Bays 41 & 42 S1 Building: Bays 4, 5, and 8 S2 Building: Bay 30 centrifuge S3 Building: Bay 32 (Kettle) reactor and centrifuge Tank Farm: Tanks HW-1 and HW-2 Methylene Chloride was removed from the description of the six vertical fixed-roof storage tanks.
2	1	No change other than numbering
3	--	Deleted, as the referenced equipment has been removed.
4	2	Requirement to monitor the flow rate of the scrubbing medium has been added if the facility is operating without the RTO Control System
5	3	No change other than numbering.
--	4	Since the facility is being allowed to operate without the RTO, the temperature specifications from the October 20, 2003 SOP are being restored. They had been removed from the permit after the processes in Buildings S1 and S3 were required to be connected to the RTO in the August 17, 2005 SOP. The facility is required to monitor reactor and exit vapor temperatures when the RTO is not in operation.
6	5	No change
7	6	Exception provided for Alternate Operating Scenario, provided that facility-wide VOC emissions do not exceed 25 tons/yr
--	7	Addition of Alternate Operating Scenario (this is the main change to the permit)
8 –12	8 –12	No change

Condition Number (9/27/13 SOP)	Condition Number (Draft Permit)	Description of Change
13, 15	13	The approved fuel and specifications were changed and combined in one condition. The emergency generator and fire pumps are authorized to burn 0.5% sulfur distillate oil, but the facility actually uses ultra-low sulfur diesel fuel. The new Condition 13 allows the facility to use either or both fuels.
14	14	Update in format according to new boilerplate condition
16	15	Updated with specifications for ASTM-D975 S15 diesel fuel
--	16	This condition was added to prohibit the storage, processing, use, or production of methylene chloride (for MACT Subpart I applicability) or any Hazardous Air Pollutant listed in Table 1 to Subpart VVVVVV of Part 63. Methylene chloride is also included in Table 1. The facility had previously reported that they were subject to MACT Subparts I and VVVVVV.
17 - 20	17 – 20	No change
21	21	Phrase was added “and/or from the bypass exhaust as provided in Condition 7” so that this limit also applies to non-fugitive process emissions that are not vented to the RTO
23 – 26	22 – 25	No change other than numbering.
27	43	Toxics condition was moved to the State Only Enforceable section of the permit.
28, 30-32	27 – 30	No change other than numbering
33	--	This condition was removed since initial testing was conducted on 2/14/07.
34	--	This condition was removed since initial testing was conducted on 2/14/07..
35	31	The RTO may need to be retested, so this requirement has been retained.
36	32	Tests at the inlet of the RTO will be required every five years to verify emission factors, starting from the date this permit is issued. The previous permit used November 22, 2005, the date of the initial testing, with the requirement that testing be completed every five years after that date. Since there has been a gap in testing, the clock is being reset with this permit. Note that the RTO may or may not be operating when this test is performed.
37	--	Building S5 has been constructed, so this Condition is no longer applicable.
38	33, 44	Recordkeeping requirements are essentially the same. The requirements pertaining to toxic pollutants were split into a separate condition in the state only enforceable section of the permit.
39	35	Testing requirement – no change

Condition Number (9/27/13 SOP)	Condition Number (Draft Permit)	Description of Change
40	45	Reporting requirement for process changes involving toxic air pollutants
41	34	Reporting requirement for process changes involving VOC
42 – 48	38 – 42	General Conditions – only format changes

D. Project Schedule

Date permit application received in region: July 1, 2016
Date application was deemed complete: September 6, 2016
Proposed construction commencement date: N/A
Proposed start-up date: Upon permit issuance

II. Emissions Calculations – In the July 1, 2016 application, UniTao submitted sample calculations used by the previous owner for a batch process. Product-specific emission factors will be developed based on this model after production has recommenced. Testing will be required every 5 years to confirm the validity of the emission factors.

III. Regulatory Review

The proposed project is not a major new source or a major modification nor does the proposed project trigger Article 6 applicability or PSD or Nonattainment requirements.

A. Criteria Pollutants

No criteria pollutant modeling was conducted since the facility is not a suspected NAAQS violator and there is no increase in uncontrolled emissions as a result of this change.

B. Toxic Pollutants

All toxic emissions are exempt by 9 VAC 5-80-1120 E of the Regulations. The generators on site are subject to MACT Subpart ZZZZ, but since this is an area source of HAP, the MACT provisions are non-delegated. MACT Subpart ZZZZ has been listed in the cover letter in accordance with current boilerplate procedures.

B.I. Chemical submitted an initial notification to EPA Region III stating that the facility was subject to the requirements of MACT VVVVVV (Area Source Chemical Manufacturing) on November 14, 2013. Since that time, the facility has not used methylene chloride, and does not have plans to use it in the future. The permittee has request an applicability determination from EPA Region III (in a letter dated August 29, 2016) to verify that the facility is no longer subject to MACT Subparts I and VVVVVV due to the discontinuation of methylene chloride use. A condition has been added to the SOP prohibiting the storage, processing, use or production of methylene chloride (subject to MACT Subpart I) or any HAP listed on Table 1 to Subpart VVVVVV of Part 63 (which includes methylene chloride). This will ensure that methylene chloride use will not resume without an amendment or modification of the permit and any appropriate notification.

C. Control Technology

The proposed control strategy – regenerative thermal oxidizer - is considered to be the Best Available Control Technology (BACT) for this source type. The condensers and scrubbers installed for production bays in Buildings S1-S3 constituted BACT at the time they were permitted, so allowing them to bypass the RTO Control System does not constitute a relaxation of the original BACT, provided that the facility-wide VOC emissions remain below 25 tons/yr. The permittee must also resume temperature specifications and monitoring (reactor and condenser temperature as well as scrubber flow rate and

pH) if the condensers and scrubbers are used instead of the RTO. If the facility wishes to extend the ability to operate without the installed RTO Control System in excess of 25 tons VOC per year, this will be considered a change in the method of operation, and a new BACT analysis will be required.

IV. Initial Compliance Determination (including references)

A. Stack Testing – Initial stack testing of HCl and SO_2 from the RTO acid gas scrubber was completed on February 14, 2007. Those conditions were removed from this permit.

B. VEEs – Initial VEEs have already been completed.

V. Continuing Compliance Determination

A. CEMS – Not required by MACT or by a state regulation.

B. Recordkeeping – No changes to current recordkeeping requirements as a result of this change. Recordkeeping requirements involving toxic air pollutants have been designated as state-only enforceable.

C. Further Testing – Every five years, starting from the date of this permit, the facility is required to verify emission factors through testing at the inlet of the RTO. This requirement is carried over from the previous permit, which specifies the starting date as November 22, 2005. The last emission factor verification test occurred on August 26, 2010, which would make the next test due on August 26, 2015, according to the permit. However, the facility had been curtailing production prior to ceasing operations leading up to the sale to UniTao Pharmaceuticals in 2014. Production will recommence on a very small scale, so the clock has been reset. Note that the test can be performed whether or not the RTO is in operation.

VI. Public Participation

Since the proposed permit is being processed as a significant SOP amendment, a 30 day public comment period is required. A public notice will be published in The Progress-Index on September 26, 2016 with a 30 day public comment period from September 26, 2016 to October 26, 2016, and a copy of the final permit will be sent to EPA Region III.

VII. Other Considerations

A. File Consistency Review – The September 27, 2013 permit is the basis for this permit.

B. PRO Policy Consistency Review – N/A

C. Confidentiality – None requested by the source.

D. Permit History – This permit will supersede the September 27, 2013 permit. The prior permit history is as follows:

September 27, 2013 – Minor amendment to the SOP to remove the 300 hour limit per year when using Methylene Chloride (related to MACT Subpart I).

April 19, 2007 – Minor amendment to lower the RTO set point temperature from 1650 ºF to 1550 ºF. Stack testing conducted in February 2007 indicated that the 95% control efficiency requirements were met at the lower temperature, so the facility requested the change in order to decrease natural gas consumption by the RTO.

October 23, 2006 – Significant amendment to the SOP for the addition of the S5 building. The RTO control efficiency was reduced from 97% to 95% based on stack testing. A 20 ppm SO_2 limit was added to the 50% control efficiency requirement for the RTO acid gas scrubber. Hourly process emissions were recalculated based on the assumption that 10% of batch process emissions occurred during any one hour vs. the previous assumption of 20%.

August 17, 2005 – Replacement of the facility's "MACT Control Air System" consisting of carbon beds and scrubbers with an RTO Control System. Temperature specifications and monitoring for the condensers were removed from the permit, since emissions would be routed to the RTO, with a minimum destruction efficiency of 97%.

October 20, 2003 – The original SOP was issued on October 20, 2003, one day before the compliance date with MACT Subpart GGG, to establish synthetic minor source status.

March 28, 2003 – NSR permit modification incorporated miscellaneous equipment. The previously permitted 750 kW emergency diesel generator was removed. At this point, the facility was major for Hazardous Air Pollutants and synthetic minor for Criteria Pollutants.

February 15, 2002 – Removal of #2 oil and #6 oil as approved fuels for the boilers; removal of storage tanks.

November 15, 2001 – Connection of the Hydrogenation Building (S2) to the MACT Air Control System.

May 30, 2001 – Addition of process equipment and a 750 kW emergency diesel generator, as well as incorporation of an existing, previously exempt 650 kW emergency diesel generator.

February 23, 2000 – NSR permit authorizing production increase and addition of control equipment (later referred to as the "MACT Air Control System").

June 30, May 5, and January 22, 1999 , August 19, 1997 , and August 12 and May16, 1996 – Amendments for relocation of process steps, increases in permitted production levels, and the temporary lowering of a facility stack during installation of ground level control equipment.

April 18, 1996 - Permit to install 3 new batch trains, construction of the Specialty Building (S3)

February 8, 1994 – Permit to construct the Hydrogenation Building (S2)

July 29, 1993 – First facility-wide permit issued to B.I. Chemicals, Inc.; hourly emission limits increased as a result of stack testing

November 6, 1992 – Installation of 15,000 gallon guaiacol tank

March 20, 1991 – Increase in production and installation of two toluene storage tanks

May 8, 1985 – Addition of batch trains.

January 6, 1982 – This permit was for a product dryer.

January 28, 1981 – The ownership had changed to Lee Laboratories/Infracorp, Ltd. by the time this permit was issued to modify one of the batch reaction trains.

November 1, 1977 – The original construction permit for the facility, issued to Hexagon/Lee Laboratories. Only one building contained process equipment (S1).

VIII. Recommendations

Based on the information submitted, it is recommended that this permit be issued. Recommendations and limitations are provided in the draft permit letter.

Regional Engineer:

Date:

Reviewing Engineer:

Date:

Attachments: Permit application